

**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:  
Robert Hofmeister *et al.*

Serial No.: 10/580,660

Filed: May 26, 2006

For: COMPOSITIONS COMPRISING  
POLYPEPTIDES

Group Art Unit: 1643

Examiner: Unknown

Atty. Dkt. No.: DEBE:066US

Confirmation No.: 1727

CERTIFICATE OF ELECTRONIC SUBMISSION

DATE OF SUBMISSION: October 30, 2006

**INFORMATION DISCLOSURE STATEMENT**

**MS AMENDMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56, it is respectfully requested that this Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 be considered by the Examiner and made of record. Copies of the listed documents required by 37 C.F.R. § 1.98(a)(2) are enclosed for the convenience of the Examiner.

In accordance with 37 C.F.R. § 1.97(g), (h), this Information Disclosure Statement is not to be construed as a representation that a search has been made, and is not to be construed to be

an admission that the information cited is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

The present Information Disclosure Statement is being filed prior to the receipt of a first Official Action reflecting an examination on the merits, and hence is believed to be timely filed in accordance with 37 C.F.R. § 1.97(b). No fees are believed to be due in connection with the filing of this Information Disclosure Statement, however, should any fees under 37 C.F.R. § 1.16 to 1.21 be deemed necessary for any reason relating to these materials, the Commissioner is authorized to deduct the appropriate fees from Fulbright & Jaworski Deposit Account No.: 50-1212/DEBE:066US.

Applicants respectfully request that the listed documents be made of record in the present case.

Respectfully submitted,



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Attorney for Applicants

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Date: October 30, 2006

Form PTO-1449 (modified)		Atty. Docket No. <b>DEBE:066US</b>	Serial No. <b>10/580,660</b>
List of Patents and Publications for Applicant's  INFORMATION DISCLOSURE STATEMENT  (Use several sheets if necessary)		Applicant <b>Robert Hofmeister <i>et al.</i></b>	
		Filing Date: <b>May 26, 2006</b>	Group: <b>1643</b>
U.S. Patent Documents <i>See Page 1</i>	Foreign Patent Documents <i>See Page 1</i>	Other Art <i>See Page 1-2</i>	

### U.S. Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Name	Class	Sub Class	Filing Date of App.

### Foreign Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Country	Language
/M.N./	B1	EP 1348715	11/19/03	Europe	English
/M.N./	B2	WO 99/54440	10/28/99	WIPO	English

### Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
/M.N./	C1	Arndt <i>et al.</i> , "Factors Influencing the Dimer to Monomer Transition of an Antibody Single-Chain Fv Fragment," <i>Biochemistry</i> , 37:12918-12926, 1998.
/M.N./	C2	Bruhl, "Depletion of CCR5-expressing cells with bispecific antibodies and chemokine toxins: a new strategy in the treatment of chronic inflammatory diseases and HIV," <i>J Immunol.</i> , 166:2420-2426, 2001.
/M.N./	C3	Hoffman <i>et al.</i> , "Serial Killing of tumor cells by cytotoxic T cells redirected with a CD19-/CD3-bispecific single-chain antibody construct," <i>International Journal of Cancer</i> , 115:98-104, 2005.
/M.N./	C4	Jager <i>et al.</i> , "Immune monitoring of tumor cell elimination from malignant ascites during immunotherapy with trifunctional bispecific antibodies," <i>Eur. J. Cancer</i> , 37:S60, 2001.
/M.N./	C5	Kretschmar <i>et al.</i> , "High-level exprssion in insect cells and purification of secreted monomeric single-chain Fv antibodies," <i>J of Immunological Methods</i> , 195:93-101, 1996.
/M.N./	C6	Kufer <i>et al.</i> , "Construction and biological activity of a recombinant bispecific single-chain antibody designed for therapy of minimal residual colorectal cancer," <i>Cancer Immunol. Immunother.</i> , 45:193-197, 1997.
/M.N./	C7	Lee <i>et al.</i> , "Reversible Dimer Formation and Stability of the Anti-tumour Single-chain Fv Antibody MFE-23 by Neutron Scattering, Analytical Ultracentrifugation, and NMR and FT_IR Spectroscopy," <i>J. Mol. Biol.</i> , 320:107-127, 2002.

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EXAMINER: /Meera Natarajan/

DATE CONSIDERED: 04/27/2011

EXAMINER: INITIAL IF REFERENCE CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED. INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.

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Exam. Init.	Ref. Des.	Citation
/M.N./	C8	Loeffler <i>et al.</i> , "Efficient elimination of chronic lymphocytic leukaemia B cells by autologous T cells with a bispecific anti-CD19/anti-CD3 single-chain antibody construct," <i>Leukemia</i> , 17:900-909, 2003.
/M.N./	C9	Loffler <i>et al.</i> , "A recombinant bispecific single-chain antibody, CD19 X CD3, induces rapid and high lymphoma-directed cytotoxicity by unstimulated T lymphocytes," <i>Blood</i> , 95:2098-2103, 2000.
/M.N./	C10	Luellau <i>et al.</i> , "Development of a downstream process for the isolation and separation of monoclonal immunoglobulin A monomers, dimers and polymers from cell culture supernatant," <i>J. Chromatography</i> , 796:165-175, 1998.
/M.N./	C11	Mack <i>et al.</i> , "A small bispecific antibody construct expressed as a functional single-chain molecule with high tumor cell cytotoxicity," <i>PNAS</i> 92:7021-7025, 1995.
/M.N./	C12	Mack <i>et al.</i> , "Biologic properties of a bispecific single-chain antibody directed against 17-1A (EpCAM) and CD3: tumor cell-dependent T cell stimulation and cytotoxic activity," <i>J Immunol.</i> , 158:3965-3970, 1997.
/M.N./	C13	Maletz <i>et al.</i> , "Bispecific Single-Chain Antibodies as Effective Tools for Eliminating Epithelial Cancer Cells From Human Stem Cell Preparations by Redirected Cell Cytotoxicity," <i>International Journal of Cancer</i> , 93:409-416, 2001.
/M.N./	C14	Schoberth <i>et al.</i> , "A New Class of Trifunctional Bispecific Antibodies Mediated Efficient Immunological Purging of Peripheral Blood Stem Cells," <i>Eur. J. Cancer</i> , 37:S51, 2001.
/M.N./	C15	Worn <i>et al.</i> , "Stability Engineering of Antibody Single-Chain Fv Fragments," <i>J Mol Biology</i> , 305:989-1010, 2001.

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